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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/869,630 | 09/21/2001 | Peter Knox | PA 9847 | 5704 |

36335 7590 09/10/2004

AMERSHAM HEALTH
IP DEPARTMENT
101 CARNEGIE CENTER
PRINCETON, NJ 08540-6231

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| EXAMINER |
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LAM, ANN Y

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| ART UNIT | PAPER NUMBER |
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1641

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

94-

Office Action Summary

Application No.

09/869,630

Applicant(s)

KNOX ET AL.

Examiner

Ann Y. Lam

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 3-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 claims a competition assay, but does not claim a competing reagent or competing analyte and does not claim with what it is competing.

Claim 3 depends from itself and is therefore indefinite. Claim 4 is indefinite for the same reason since it depends from claim 3.

Claim 4 claims a hybridization assay but does not claim whether a nucleic acid is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Balamore, WO 95/27438.

Balamore discloses an in vitro method (see page 9, lines 26-30) comprising labeling a biological molecule with hyperpolarized ^{129}Xe (see page 6, lines 12-20), and observing a magnetic resonance spectrum (NMR) and/or NMR image of the hyperpolarized xenon in the environment of the biological molecule (see page 7, lines 6-12), wherein the biological molecule is an assay reagent taking part in an assay method (column 7, lines 20-22, and page 8, lines 9-10 and 22-23.) Since assay means an analysis, the method of detecting and imaging the noble gas as taught by Balamore is considered an assay since it is an analysis. Since reagent means a substance used because of its chemical or biological activity, the biological molecule in Balamore is an assay reagent since it is a substance used in the analysis because of its biological activity.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 3-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sabbadini, 6,210,976, in view of Balamore, WO 95/27438.

Sabbadini disclose the invention substantially as claimed. More specifically, Sabbadini discloses an in vitro method comprising observing a magnetic resonance spectrum (NMR) and/or NMR image (column 4, line 13-16) as the detection step in an immunoassay (column 4, line 4; and column 6, line 64 – column 7, line 6.)

As to claims 3 and 4, the assay is an immunoassay or binding assay (column 4, line 4; and column 6, line 66.)

As to claim 5, the molecule is a peptide or a protein (column 4, line 4; and column 6, line 64 – column 7, line 6.)

However, Sabbadini does not explicitly disclose that the label used in the NMR spectroscopy is hyperpolarized ^{129}Xe .

Balamore discloses an in vitro method (see page 9, lines 26-30) comprising labeling a biological molecule with hyperpolarized ^{129}Xe (see page 6, lines 12-20), and observing a magnetic resonance spectrum (NMR) and/or NMR image of the hyperpolarized xenon in the environment of the biological molecule (see page 7, lines 6-12.)

It would have been obvious to one of ordinary skill in the art to utilize hyperpolarized ^{129}Xe as the detectable NMR label as taught by Balamore^{in the method of Sabbadini} since it is an alternative NMR detectable label.

And as to claims 6-9, Sabbadini also does not disclose that the hyperpolarized ^{129}Xe is enriched at a level of 40% or more, or that the degree of hyperpolarisation is

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8% or more, or that the method is performed in a solution wherein the solvent has a viscosity in the range of 700 to 1500 mPs, or that the pressure of the xenon gas is at least 5 bar.

Since these conditions are generally disclosed in Balamore and these claimed ranges appear to be the optimum or workable ranges, it would have been obvious to modify the Sabbadini reference to provide these ranges since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum of workable ranges involves only routine skill in the art (In re Aller, 105 USPQ 233.)

Response to Arguments

Applicant's arguments with respect to the above rejected claims have been considered but are moot in view of the new ground(s) of rejection.

Balamore discloses that the biological molecule is an assay reagent taking part in an assay method, as explained above.

The rejection under Weissleder is withdrawn.

With respect to the 112 rejection for the term "environment of the biological molecule", the rejection is hereby withdrawn.

Rejection of claim 2 is moot since claim 2 is cancelled.

Examiner reasserts that claims 3 and 4 are indefinite for the reasons set forth above.

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Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.




CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800-1641
9/7/04